



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2015

Safe Orthopaedics
% Mr. Pierre Dumouchel
Industrialization Director / QARA Director
Parc des Bellevues, Allée R. Luxembourg – Le Califormie
95610 Eragny sur Oise
FRANCE

Re: K151921

Trade/Device Name: SteriSpine™ PS
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: July 23, 2015
Received: July 27, 2015

Dear Mr. Dumouchel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151921

Device Name

SteriSpine™PS

Indications for Use (Describe)

The SteriSpine™PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. SteriSpine™PS System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510k
SteriSpine™ PS

510(k) SUMMARY

510k	Traditional
Submitted by	Safe Orthopaedics Parc des Bellevues Allée R. Luxembourg - Le Californie 95610 Eragny sur Oise – FRANCE
Contacts	Pierre DUMOUCHEL Industrialization Director / QARA Director p.dumouchel@safeorthopaedics.com +33 (0) 1 34 21 50 00 Isabelle DRUBAIX Regulatory contact idee-consulting@nordnet.fr +33 (0)3 21 05 64 23
Date Prepared	October 6 th 2015
Common Name	Pedicle screw spinal system
Trade Name	SteriSpine™PS
Classification Name	Pedicle screw spinal system
Class	III
Product Code	NKB, MNI, MNH, KWP
CFR section	888.3070
Device panel	Orthopedic
Legally marketed predicate devices	Primary predicate device: Synergy VLS (K011437) manufactured by Interpore Cross International. Other predicate device: STERISPINE™ PS manufactured by SAFE ORTHOPAEDICS (K112453)
Indications for use	The SteriSpine™PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. SteriSpine™PS System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.
Description of the device	SteriSpine™PS system includes pedicle screws (multiaxial and cannulated) and rods (straight and prebent). Implantable components of SteriSpine™PS system are made of Titanium Ti-6Al-4V ELI according to ASTM F136. The SteriSpine™PS range of products is supplied sterile with a sterile single-use set of surgical instruments.
Technological Characteristics	The purpose of this 510(k) submission is to obtain clearance for a new extended head max cannulated screw and the associated extended head screwdriver as well as the addition of a «window» to the external packaging of SteriSpine™ PS devices supplied sterile.

Performance data	SteriSpine™ PS conforms to special control established for Pedicle Screw spinal system. Mechanical testing was conducted according to ASTM F1717 and ASTM F1798 Standard. Performed mechanical testing includes the following: Static Compression, static torsion, dynamic torsion, static slipping, static bending and static rotation. The following non-clinical tests were conducted: Packaging validation according to ISO 11607-1 and 11607-2 and sterilization revalidation according to ISO 11137-1, 11137-2 and 11137-3. No clinical data has been presented.
Discussion of Testing	Mechanical testing demonstrates comparable mechanical properties to the predicate devices.
Conclusion	Non clinical performance testing demonstrates that the added devices are substantially equivalent to predicate devices in terms of intended use, materials, design and function.